(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

154 (new). The method of claim 153 wherein said chronic immune mediated disorder is an autoimmune disease.

155 (new). The method of claim 153, wherein said chronic immune mediated disorder is diabetes mellitus.

156 (new). The method of claim 4 wherein the first dose of at least one immunogen in at least one of said immunization schedules is given when the mammals are less than 42 days old.

157 (new). The method of claim 5 in which the first dose of at least one immunogen in at least one of said immunization schedules is given when the mammals are less than 14 days old.

158 (new). The method in claim 153 wherein at least one group receives, according to its immunization schedule, more than

one dose of at least one immunogen.

159 (new). The method of claim 153, wherein for at least one immunogen in at least one schedule, the total dosage during the first 112 days after birth is substantially greater than that required for protection against the infectious disease with which it is associated.

160 (new). The method of claim 1 wherein in at least one schedule at least one immunogen is administered by a route other than intravenously.

161 (new). The method of claim 153 wherein in at least one schedule at least one immunogen is administered subcutaneously, intradermally, or intramuscularly.

162 (new). The method of claim 153 wherein in at least one schedule at least one immunogen is administered other than as an immunogen of a live vaccine.

163 (new). The method of claim 153 wherein in at least one schedule at least one immunogen is not a BCG immunogen.

164 (new). The method of claim 153 wherein at least one immunogen of said subject immunization schedule which was also included in said lower risk schedule is one other than a pertussis immunogen.

165 (new). The method of claim 153 wherein the incidence of the disorder in said groups is compared.

166 (new). The method of claim 153 wherein the method is part of a production process to test vaccine lots for efficacy or safety.

167 (new). The method of claim 153 wherein the method is part of a development process or clinical trial of a vaccine to test a vaccine for safety or efficacy.

168 (new). The method of claim 153 wherein said mammals are human.

169 (new). The method of claim 153 wherein said mammals are rodents and diabetes has not been chemically induced by

streptozotocin.

170 (new). The method of claim 153 wherein said mammals are NOD mice or BB rats.

171 (new). The method of claim 153 wherein the comparison of (I) is prospective.

172 (new). The method of claim 153 wherein said mammals are randomized in said groups.

173 (new). The method of claim 153 wherein at least one said groups receives at least one potentially pharmaceutically acceptable dose of each at least two potentially pharmaceutically acceptable immunogenic agents which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a non-pediatric immunogen.

174 (new). The method of claim 153 wherein one screened schedule provides at least one immunogen not provided by another screened schedule or fails to provide at least one immunogen provided by another screened schedule.

175 (new). The method of claim 153 wherein one screened schedule provides a higher or lower dose of at least one immunogen than that provided for the same immunogen in said another screened schedule.

176 (new). The method of claim 153 wherein one screened schedule provides a different number of doses of at least one immunogen than is provided for the same immunogen by another screened schedule.

177 (new). The method of claim 153 wherein one screened schedule provides at least one dose of at least one immunogen at a later or earlier time from birth than the corresponding dose of the same immunogen is provided by another screened schedule.

178 (new). The method of claim 153 wherein at least one group first receives at least one immunogen starting after 41 days of life.

179 (new). The method of claim 153 wherein at least one immunogen is first administered to at least one group starting after 41 days after birth but before 180 days after birth.

180 (new). The method of claim 153 wherein at least the majority of the mammals in at least one group did not develop the infectious diseases which are associated with said immunogens.

181 (new). The method of claim 153 wherein mammals are excluded from a treatment group if:

i) said mammals have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or

ii) said mammals have substantial levels of at least one surrogate marker of an autoimmune disease even though the mammals had not been previously diagnosed as having an autoimmune disease, or

iii) said surrogate marker was substantially increased following a previous vaccination, infection or other immunologic challenge.

182 (new). The method of claim 153, wherein both a pediatric immunogen and a non-pediatric immunogen are administered to at least one group.

183 (new). The method of claim 153 in which the mammals are humans and the groups are compared for a period from first administration for at least one year.

184 (new). The method of claim 153 in which the mammals are humans and the groups are compared from first administration until at least 5 years of age.

185 (new). The method of claim 153 in which the mammals are rodents and groups are compared from first administration until at least 24.5 weeks of age.

186 (new). The method of claim 153 wherein in at least one schedule at least one immunogen is administered with a depot adjuvant.

187 (new). The method of claim 153 wherein the disorder is not an immune-mediated cancer.

188 (new). The method of claim 153, further comprising determining whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence, or frequency of the disorder.

189 (new). The method of claim 153, wherein the effect of the schedules on the incidence, prevalence, or frequency of the disorder is determined at least one year after at least two of the screened immunization schedules first differ.

190 (new). The method of claim 153 in which the subject immunization schedule is identical to one of said screened schedules.

191 (new). The method of claim 153 where said subject immunization schedule also protects the subject against at least one infectious disease.

192 (new). The method of claim 153 where said subject immunization schedule also protects the subject against at least two infectious diseases.

193 (new). The method of claim 153 wherein the ability of said screened immunization schedules to protect against an infectious disease is also compared.

194 (new). The method of claim 153 wherein at least one group receives an immunogen at a time sufficiently early enough to substantially reduce the incidence of said disorder, sufficient number of mammals are followed after immunization for a sufficiently long interval to ensure that said mammals have an effect lasting for a clinically significant period of time after discontinuation of immunization, and the method does not involve the administration of an live organism leading to the infection of mammals for the duration of the time they are followed.

195 (new). The method of claim 153, wherein said chronic immune mediated disorder is diabetes mellitus, wherein the

mammals are humans, and wherein the effect of the schedules on the incidence, prevalence, frequency of the disorder is determined at least one year after said first and second immunization schedules differ.

196 (new). The method of claim 195 wherein said mammals are randomized in said groups.

197 (new). The method of claim 195 wherein both a pediatric immunogen and a non-pediatric immunogen are administered to at least one group.

198 (new). The method of claim 195 wherein at least one immunogen is administered one other than as an immunogen of a live vaccine and wherein the first dose in at least one of said immunization schedules is given when the mammals are less than 42 days old.

199 (new). The method of claim 195 wherein the incidence of the disorder in said groups is compared and wherein at least one immunogen is first administered to at least one group starting after 41 days after birth but before 180 days after birth.

200 (new). The method of claim 195, further comprising determining whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence, or frequency of the disorder, wherein at least one immunogen is administered one other than as an immunogen of a live vaccine.

201 (new). The method of claim 195 wherein incidence of the disorder in said groups is compared for at least two different chronic immune-mediated disorders, one of which is diabetes mellitus.

202 (new). The method of claim 153 where at least one screened schedule calls for immunizing mammals starting at less than 42 days after birth and the screened immunization schedules differ as to the age at the time of the first dose of at least

one other immunogen.

203 (new). The method of claim 202 where said mammals in at least one schedule receive hepatitis B immunogen prior to 42 days after birth.

204 (new). The method of claim 153 where said comparison comprises compensation for at least one confounding variable.

205 (new). The method of claim 204 where the analysis includes compensation for confounding variables selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of diabetes or a second chronic immune mediated disorder, maternal infections while the mammal was in utero, infections during the first 12 months of life, size of the mammal at birth, gestational age of the mammal at birth, and exposure to vaccines.

206 (new). The method of claim 153 in which, in (I)(b), the incidence, prevalence or frequency of at least one chronic immune-mediated disorder is compared, and the lower risk screened immunization schedule is associated with a lower incidence, prevalence or frequency of that disorder.

207 (new). The method of claim 153 where the first and second groups differ by at least one of the following differences:

a) the presence of at least one immunogen in the schedule for one group and not the other;

b) a difference in the size of the dose of at least one immunogen administered to both groups;

c) a difference in the number of doses of at least one immunogen administered to both groups; or

d) a difference in the day of administration, relative to birth, of the first dose of at least one immunogen administered to both groups.

208 (new). The method of claim 207 where at least one of said differences (a)-(d) relates to at least one immunogen other

than a BCG immunogen.

209 (new). The method of claim 207 where at least one of said differences (a)-(d) relates to at least one immunogen other than a BCG or measles immunogen.

210 (new). The method of claim 207 where at least one of said differences (a)-(d) relates to at least one immunogen other than a BCG, measles, mumps, rubella, smallpox, diphtheria, tetanus, pertussis or polio immunogen.

211 (new). The method of claim 207 where at least difference (a) applies.

212 (new). The method of claim 207 where at least difference (b) applies.

213 (new). The method of claim 207 where at least difference (c) applies.

214 (new). The method of claim 207 where at least difference (d) applies.

215 (new). The method of claim 207 where at least two of differences (a)-(d) apply.

216 (new). The method of claim 207 where at least three of differences (a)-(d) apply.

217 (new). The method of claim 207 where all of differences (a)-(d) apply.

218 (new). The method of claim 207 where the chronic immune-mediated disorder is diabetes.

219 (new). The method of claim 207 where the subjects are human.

220 (new). The method of claim 219 where the mammals of said groups are human.

221 (new). The method of claim 207 wherein the effect of the schedule on the incidence, prevalence, or frequency of the disorder is observed at least one year after the first difference in immunization between the groups is manifest.

222 (new). The method of claim 220 wherein the effect of

the schedule on the incidence, prevalence, or frequency of the disorder is observed at least one year after the first difference in immunization between the groups is manifest.

223 (new). A method of immunizing a mammalian subject which comprises:

(I) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule,

and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune

mediated disorder(s),

where the first dose of at least one infectious disease-causing organism associated immunogen given to both groups is given sooner after birth according to the first screened immunization schedule than according to the second schedule (each such immunogen so administered to said first group being hereafter referred to as an "early" immunogen regardless of its time of administration in the second group), and

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said early infectious disease-causing organism-associated immunogens is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

224 (new). The method of claim 223 in which the disorder is an autoimmune disease.

225 (new). The method of claim 224 in which the disorder is diabetes mellitus.

226 (new). The method of claim 224 in which the disorder is SLE.

227 (new). The method of claim 224 in which at least one comparison (b) is made at least one year after first administration of an early immunogen to said mammals.

228 (new). The method of claim 224 where said mammalian subject is or said mammals are humans.

229 (new). The method of claim 225 where said mammalian subject is or said mammals are humans.

230 (new). The method of claim 229 in which at least one comparison (b) is made at least one year after first administration of an early immunogen to said mammals.

231 (new). The method of claim 230 where at least one of

said early immunogens is one other than BCG or pertussis immunogen.

232 (new). The method of claim 223 where the first dose of at least one early immunogen is given according to a screened schedule starting at less than 42 days after birth.

233 (new). The method of claim 225 where the first dose of at least one early immunogen is given according to a screened schedule starting at less than 42 days after birth.

234 (new). The method of claim 230 where the first dose of at least one early immunogen is given according to a screened schedule starting at less than 42 days after birth.

235 (new). The method of claim 231 where the first dose of at least one early immunogen is given according to a screened schedule starting at less than 42 days after birth.

236 (new). The method of claim 232 where at least two immunogens are administered according to said subject immunization schedule, and such immunogens include (1) a first immunogen which was given prior to 42 days after birth to said first and second groups, and (2) a second and different immunogen which is an early immunogen.

237 (new). The method of claim 230 further comprising (III) screening said subject, during or after receipt of said third schedule, for the development of diabetes.

238 (new). The method of claim 230 where the incidence of diabetes is compared.

239 (new). The method of claim 223 where at least two of the screened schedules also differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

240 (new). The method of claim 223 where at least one infectious disease-causing organism-associated immunogen is administered to said subject so as to protect said subject against said infectious disease.

241 (new). The method of claim 240 where at least two different immunogens are administered so as to protect the subject against at least two different infectious diseases.

242 (new). The method of claim 240 where the immunogen protective against said infectious disease is an early immunogen.

243 (new). The method of claim 223 where the screened schedules do not differ by either the presence of at least one immunogen or the number of doses of at least one immunogen.

244 (new). The method of claim 230 where said lower risk of development of diabetes is evidenced by a lower incidence or frequency, or a slower onset, of diabetes.

245 (new). A method of immunizing a mammalian subject which comprises

(I) (a) immunizing a first group of mammals with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule,

(b) immunizing at least a second group of mammals with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, the first and second groups being of the same species, and

(c) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and ~~second~~ groups,

as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

where the first dose of at least one infectious disease-causing organism-associated immunogen given to both groups is given sooner after birth according to the first screened immunization schedule than according to the second schedule (each such immunogen so administered to said first group being hereafter referred to as an "early" immunogen regardless of its time of administration in the second group),

and

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said early, infectious disease-causing organism-associated immunogens is administered in accordance with said lower risk screened immunization schedule, resulting in a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

246 (new). The method of claim 245 where one of said chronic immune-mediated disorders is diabetes,
where said mammalian subject is or said mammals are humans,
where said comparison (b) is made at least one year after first administration of said immunogen to said mammals.

247 (new). The method of claim 246 where at least one of said early immunogens is one other than BCG or pertussis immunogen.

248 (new). A method of protecting a mammalian subject, by immunization, against at least one infectious disease while reducing the risk of said subject thereby developing a chronic immune mediated disorder, which comprises:

(I) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with

one or more doses of one or more infectious disease-causing organism- associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule,

and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

where the first dose of at least one infectious disease-causing organism associated immunogen given to both groups is given sooner after birth according to the first screened immunization schedule than according to the second schedule (each such immunogen so administered to said first group being hereafter referred to as an "early" immunogen regardless of its time of administration in the second group), and

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said

early infectious disease-causing organism-associated immunogens is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule,

at least one of the immunogens of (II) being protective against said infectious disease when administered according to aid third immunization schedule, said third schedule presenting a reduced risk of said subject developing a chronic immune mediated disorder relative to said second schedule.

249 (new). The method of claim 248 where one of said chronic immune-mediated disorders is diabetes,
where said mammalian subject is or said mammals are humans, and where said comparison (b) is made at least one year after first administration of said immunogen to said mammals.

250 (new). A method of immunizing a mammalian subject which comprises:

(I) screening a plurality of immunization schedules, by
(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule,
and

(b) comparing the incidence, frequency, prevalence, or time of onset of said chronic immune-mediated disorder in the first group with that in the second group,

where the first dose of at least one immunogen given to both groups is given (i) sooner after birth according to the first screened immunization schedule than according to the second schedule (each such immunogen so administered to said first group being hereafter referred to as an "early" immunogen regardless of its time of administration in the second group), or (ii) according to the first screened immunization schedule when the mammals of the first group are less than 42 days old (each such immunogen is administered to said first group being hereafter referred to as a "pre-42" immunogen regardless of its time of immunization in the second group);

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said early or pre-42 immunogens is administered in accordance with said first screened immunization schedule, and is associated with a lower incidence, frequency, or prevalence, or slower onset, of a chronic immune-mediated disorder than when said immunogen was administered according to said second screened immunization schedule.

251 (new). The method of claim 250 where one of said chronic immune-mediated disorders is diabetes,
where said mammalian subject is or said mammals are humans,
where said comparison (b) is made at least one year after first administration of said immunogen to said mammals.

252 (new). The method of claim 223 in which, in at least one screened schedule, the first dose of said immunization schedule is administered before the mammal's immune system arrives at a state of maturation comparable to that achieved at an age of 42 days after birth in a mouse or rat.

253 (new). The method of claim 223 in which, in said subject schedule, the first dose of said immunization schedule is administered before the subject's immune system arrives at a state of maturation comparable to that achieved at an age of 42 days after birth in a mouse or rat.

254 (new). The method of claim 225 in which, in at least one screened schedule, the first dose of said immunization schedule is administered before the mammal's immune system arrives at a state of maturation comparable to that achieved at an age of 42 days after birth in a mouse or rat.

255 (new). The method of claim 225 in which, in said subject schedule, the first dose of said immunization schedule is administered before the subject's immune system arrives at a state of maturation comparable to that achieved at an age of 42 days after birth in a mouse or rat.

256 (new). A method of protecting a mammalian subject, by immunization, against at least one infectious disease while reducing the risk of said subject thereby developing a chronic immune mediated disorder, which comprises:

immunizing said subject according to a subject immunization schedule, according to which one or more immunogens is administered to the subject, each immunogen being administered on one or more dates according to such schedule,

where it has previously been determined that the timing of first administration of at least one of said immunogens influences the risk of said subject thereby developing said disorder, and

where the first administration of at least one risk-influencing immunogen according to said schedule is timed so as to reduce the risk of said subject thereby developing said disorder, relative to the risk if said first administration had been at some later date.

257 (new). The method of claim 256 where said determination

was made by

(I) screening a plurality of immunization schedules, by (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule,

and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s).

258 (new). The method of claim 256 where the disorder is diabetes.

259 (new). A method of protecting a mammalian subject, by

immunization, against at least one infectious disease while reducing the risk of said subject thereby developing a chronic immune mediated disorder, which comprises:

(I) determining whether the timing of first administration of at least one immunogen protective against at least of said infectious diseases influences the risk of said subject developing said disorder, and

(II) immunizing said subject according to an immunization schedule, according to which one or more immunogens, including at least one immunogen of (I), is administered to the subject, each immunogen being administered on one or more dates according to such schedule,

where the first administration of at least one immunogen of (I) according to said schedule is timed so as to reduce the risk of said subject thereby developing said disorder, relative to the risk if said first administration had been at some later date.

260 (new). The method of claim 189 where said disorder is diabetes.

261 (new). The method of claim 260 in which at least one immunogen is first administered to said subject at less than 42 days after birth, and said determining was performed at least one year after said first immunization.

262 (new). A business method for developing safer methods of protecting humans against infectious diseases by immunizing humans with one or more doses of one or more immunogens which induce protective immunity to one or more infectious diseases when administered according to one or more immunization schedules, said method comprising

I. evaluating the association between said immunization schedule and one or more chronic immune mediated disorders by

a) comparing the incidence, prevalence or frequency of a chronic immune mediated disorder in a group comprising humans where the majority receive an immunization schedule comprising

said one or more immunogens to that in a control group comprising humans where the majority receive a different immunization schedule,

or

b) comparing the risk of said chronic immune mediated disorder associated between two or more immunization schedules,

where the comparisons each comprise a time span of at least one year after the administration of said one or more immunogens, and

II. determining one or more methods of immunization to allow safe immunization with said immunogenic agent reflective of the analysis from I.

263 (new). A business method for developing safer methods of protecting humans against infectious diseases by immunizing humans with one or more doses of one or more immunogens which induce protective immunity to one or more infectious diseases when administered according to one or more immunization schedules, said method comprising

(I) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism- associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a